

SUMMARY OF MEETING WITH JAPANESE REPRESENTATIVES ON MONDAY, MARCH 10, 2003, ABOUT FDA'S BIOTERRORISM PROPOSALS

Following FDA's publication of the Proposed Rules for Registration and Prior Notice as part of FDA's efforts to implement the new bioterrorism law, the Japanese government requested that we provide a briefing to help them understand the purpose and content of those proposals. Because I was scheduled to be in Japan to participate in a Codex Task Force meeting, I arranged (through the U. S. Embassy) a presentation on FDA's proposals that I made on the day before the Codex meeting began.

My presentation went from 10:00 a.m. to about 12:30 p.m. on Monday, March 10, 2003, at a Japanese government building in Tokyo. I used the same PowerPoint presentation that Leslye Fraser had developed for use in making presentations to other foreign governments. The meeting was attended by representatives from several agencies of the Japanese government. The meeting was also attended by representatives from several Japanese trade associations. The full list of Japanese participants is attached.

The other representatives from the U.S. government who were present during this meeting were Dr. Mike Wehr (who was at the computer) from FDA, Dick White from USTR and Bobby Richey from the Foreign Agricultural Service. Clay Hamilton and staff personnel from the U. S. Embassy were also present.

I began with a detailed presentation of the elements contained in FDA's Proposed Rule for Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness Act of 2002. This was followed by questions and comments from several of the Japanese who were in the room. The comments expressed concerns that the new requirements would pose a barrier to the entry Japanese products into the United States. I made it clear that FDA did not intend to create a trade barrier, but was instead trying to better protect consumers from unsafe foods. The questions were mainly questions for clarification and were generally similar to questions raised in our briefings in other countries.

I then presented a detailed description of the elements contained in FDA's Proposed Rule for Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness Act of 2002. I heard more expressions of concern in the comments offered by the Japanese representatives about the potential for this proposal to adversely affect Japanese exporters, including a comment that the prior notice requirement was not needed to protect U.S. consumers. I stated our view that it was necessary, but invited their comments. Here again, many questions were asked of a clarifying nature that were similar to questions we heard during our briefings in other countries.

At the end of the meeting, I emphasized that these proposals were important as part of the U.S. efforts to protect US. citizens from potential terrorist activity against food and feed. I also emphasized that it was a very high priority activity and that FDA was operating under tight time schedules. I pointed out, however, that we very much wanted to receive their comments. I also stressed the need for them to submit their comments on these two proposals by April 4, 2003, and the need to include the docket numbers on their comments.

The Japanese representatives thanked us for taking the time to explain the proposals and to respond to their questions. They also indicated that they would be submitting comments on both proposals.

/s/

Bob Lake

Attachment

Participants' List of the Meeting for
Explaining Bioterrorism Act by FDA

Mr. HASEGAWA Masao, Deputy Director for Policy Planning,
Administration, Division General Food Policy Bureau, Ministry of
Agriculture, Forestry and Fisheries

Mr. OGAWA Keigo, Section Chief, Consumers Life Division, General Food
Policy Bureau, Ministry of Agriculture, Forestry and Fisheries

Mr. NISHIURA Hiroyuki, Deputy Director, Food Industry Policy Division,
General Food Policy Bureau, Ministry of Agriculture, Forestry and
Fisheries

Mr. TSUGANEZAWA Masahiro, Assistant Director, Food Industry Policy
Division, General Food Policy Bureau, Ministry of Agriculture, Forestry
and Fisheries

Mr. AONO Moriyasu, Section Chief, International Trade and Information
Office, International Trade Policy Coordination Division, International
Affairs Department, General Food Policy Bureau, Ministry of
Agriculture, Forestry and Fisheries

Mr. MAKINO Hidefumi, Section Chief, International Trade and Information
Office, International Trade Policy Coordination Division, International
Affairs Department, General Food Policy Bureau, Ministry of
Agriculture, Forestry and Fisheries

Mr. MOTOKI Kaname, Section Chief, Food Industry Promotion Division,
General Food Policy Bureau, Ministry of Agriculture, Forestry and
Fisheries

Mr. MURAI Satoru, Section Chief, Fruit and Flower Division,
Agricultural Production Bureau, Ministry of Agriculture, Forestry and
Fisheries

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Agricultural Production Bureau, Ministry of Agriculture, Forestry and
Fisheries

Mr. KURUMISAWA Syuji, Deputy Director, Processed Food Division, Food
Agency

Ms. KIBA Takako, Official, Processing and Marketing Division, Fisheries
Agency

Mr. SANO Yoshihiko, Section Chief, Inspection and Safety Division,
Department of Food Safety, Ministry of Health, Labour and Welfare

Mr. UMEDA Hiroshi, Specialist, Quarantine Station Administration
Office, Policy Planning Division, Department of Food Safety, Ministry
of Health, Labour and Welfare

Mr. HASEBE Tatsuo, Policy Planning Division, Department of Food Safety,
Ministry of Health, Labour and Welfare

Ms. KUMAGAI Yuko, Specialist, International Affairs Division,
Minister's Secretariat, Ministry of Health, Labour and Welfare

Mr. MIYAGAWA Shoji, Deputy Director, Department of Food Safety,
Ministry of Health, Labour and Welfare

Ms. IMAI Mitsuko, First International Organizations Division, Economic
Affairs Bureau, Ministry of Foreign Affairs

Mr. ISHIGAKI Tomoaki, Legal Affairs Division, Treaties Bureau, Ministry
of Foreign Affairs

Mr. FUNAKI Yasuro, Second North America Division, North American
Affairs Bureau, Ministry of Foreign Affairs

Mr. HIRAKO Tetsuo, Provisional office for Food Safety Commission,
Cabinet Secretariat

Ms. HAMADA Tokiko, Japan Fisheries Association

Mr. SHIMOMURA Masao, Japan Fish Trade Association

Mr. YAMAGUCHI Hiroshi, National Federation of Agricultural Cooperative
Associations (ZEN-NOH)

Mr. TAZAWA Yoshinori, Japan Fruit Growers Cooperative Association

Mr. MONMA Hiroshi, Japan Food Industry Center

Mr. TUCHIYA Toshizo, Japan Fruit Foundation

Mr. HASEGAWA Naoyuki, Japan External Trade Organization (JETRO)